open end of said tubular body portion receiving said radially extending ribs of said clip member through said side wall, and a cup-shaped cap having a plurality of inwardly projecting ribs received in said grooves in said shield to adjacent said ribs on said clip member preventing retraction of said shield when said cap is located on said shield.

Please cancel Claims 2, 3, 12 and 13, without prejudice.

REMARKS

The following is responsive to the Patent Office Action mailed October 21, 2002. First, Claim 1 has been amended essentially to incorporate the subject matter of Claim 2. Claim 2 was rejected by the Examiner as being "anticipated" by U.S. Patent No. 4,894,055 of ***Sudnak*** under 35 U.S.C. § 102(b). However, the ***Sudnak*** patent ***does not anticipate*** Claim 2. The tabs or locking members 30 shown in Figure 2 of ***Sudnak*** are ***not "hook-shaped."*** Claim 1, as originally filed, recited that the clip member included "a plurality of spaced ***laterally projecting*** resilient fingers" which are not found in ***Sudnak***. However, Claim 1 has now been amended to not only recite that the fingers are "hook-shaped," but further each finger "having an outwardly inclined end portion" to clearly define the recognized meaning of "hook-shaped." Claim 1 has been further amended to recite that the opening in the channel-shaped tracks extends "through a side wall of said shield and that the outwardly inclined end portion of the hook-shaped fingers extend through the opening, providing a ***positive lock.***

In contradistinction, the ***Sudnak*** patent discloses a "tubular base member" 12 having inwardly projecting tabs or locking members 30 and that the guard member 16 includes grooves 46, relying upon a friction fit. However, in an attempt to strengthen the inner connection between the locking tabs 30 and the grooves 46, a separate "annular slip member" or ring 34 is provided which must bias the locking members or tabs 30 outwardly as shown in Figure 2. The laterally projecting resilient hook-shaped fingers provide a positive and secure

stop without the requirement of a ring or annular slip member as required in the ***Sudnak*** patent which it appears would be subject to failure. Because Claim 1 now incorporates the subject matter of Claims 2 and 3; Claims 2 and 3 have been cancelled.

Claim 11 has been similarly amended and Claims 12 and 13 have been cancelled. The same arguments above regarding Claim 1 applied to Claim 11.

Claim 21 was rejected as unpatentable over the ***Sudnak*** patent in view of U.S. Patent No. 6,203,529 of ***Gabriel, et al.*** under 35 U.S.C. § 103. The Applicant respectfully traverses the rejection of Claim 21 as filed. The amendments to Claim 21 are above are for purposes of clarification only as discussed further below. The Applicant also submits that the Examiner misapprehended Claim 21 as filed based upon the remarks following the rejection.

Claim 21 specifically claims a pen needle and safety shield assembly which is not found in the ***Sudnak*** patent. Thus, it would appear that the Examiner intended to reject Claim 21 as unpatentable over ***Gabriel, et al.*** in view of ***Sudnak***. Claim 21 recites that the tubular body portion 50 of the clip member 48 includes a plurality of radially extending ribs 56 and that the tubular body portion of the retractable shield 22 includes a plurality of radial grooves extending through the tubular body. As amended, Claim 21 now recites that the radial grooves extend through "a side wall of said tubular body portion" which the Applicant respectfully submits has the same meaning. Thus, the radial ribs 56 extend through the radial grooves 66 providing visual evidence that the shield 23 is properly mounted on the clip member as shown in Figure 1 and positively preventing rotation of the shield member on the clip member.

Assuming that the Examiner is attempting to read these limitations upon the disclosure of the ***Gabriel, et al.*** patent, it is noted that the needle carrier or hub 10 includes a small radial rib 48 and the shield 32 includes a groove 44 to prevent rotation of the shield on the hub. Thus, the ***Gabriel, et al.*** patent does not disclose a separate needle hub and clip

member as specifically recited in the claims and the groove 44 does not extend through the shield providing visual evidence of proper assembly of the shield and relying upon one rib received in a groove to prevent rotation of the shield on the hub. That is, the ***Gabriel, et al.*** patent does not include all of the claimed elements including a hub, clip member, retractable shield and cap nor the limitations discussed above. The Applicant therefore respectfully requests reconsideration of the rejection of the Claim 21.

Several of the dependent claims also patentably distinguish over the prior art. For example, Claims 4 and 14 recite that the channel-shaped tracks in the shield include an inwardly projecting resilient finger adjacent the opening which is shown at 70 in Figures 2 and 14. These fingers or tangs prevent the hook-shaped fingers from being received in the opening 68 as the shield is extended as shown in Figure 6. The Examiner has failed to cite any prior art patent disclosing this feature. This would appear to be because the groove in ***Sudnak does not extend through the side wall of the shield***. Thus, there would be no reason to include a tang or finger as shown at 70. The Applicant therefore respectfully requests reconsideration of the Examiner's rejection of Claims 4 and 14.

Dependent Claims 8, 9, 17 and 18 are directed to the U-shaped portion 54 of the clip member which provide further resiliency for the hook-shaped fingers and receive one end 55 of the spring 74 as shown in Figure 2. This additional feature of the clip member is not disclosed in any of the prior art references cited by the Examiner and appears to be either overlooked or misunderstood by the Examiner. That is, these claims are not related to the shape of the hook-shaped portions and are certainly not disclosed or suggested in U.S. Patent No. 6,416,323 of ***Grenfell, et al.*** in Figure 9. The aspirating dental syringe with needle shield disclosed in the ***Grenfell, et al.*** patent does not even include a spring or hook-shaped fingers as recited in the claims.

The Applicant therefore respectfully requests reconsideration of the Examiner's rejection of the claims as amended and allowance of this application.

Although it is believed that no fee is due for the filing of this Amendment, the Commissioner is authorized to charge our Deposit Account No. 08-2789 for any additional fees or credit the account for any overpayments regarding this Amendment.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Respectfully submitted,

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Dated: January 21, 2003

CERTIFICATE OF EXPRESS MAILING

I hereby certify that the enclosed **Amendment** is being deposited with the United States Postal Service as Express Mail, postage prepaid, in an envelope as "Express Mail Post Office to Addressee," Mailing Label No. **EV164144359US** and addressed to the Assistant Commissioner for Patents, Washington, D. C. 20231, on **January 21, 2003.**

Tracy L. Smith

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

1. (Amended) A safety shield system for a needle cannula having a lumen therethrough for transfer of fluid from a body having a generally tubular end portion, said safety shield system comprising a generally tubular clip member having a plurality of spaced laterally projecting resilient hook-shaped fingers each having an outwardly inclined end portion, a generally tubular [recipricable] reciprocable shield including a first portion surrounding said clip member, a second portion normally surrounding said needle cannula and a plurality of spaced axially extending inwardly opening channel-shaped tracks on inside surface of said shield receiving said laterally projecting resilient hook-shaped fingers of said clip member and guiding said shield axially from a first position wherein said shield second portion surrounds said needle cannula to a second position wherein said needle cannula is exposed, and a spring resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula, wherein at least one of said channel-shaped tracks includes an opening through a side wall of said shield which receives said end portion one of said fingers therethrough when said shield is first retracted to said second position and then extended to said first position by said spring and locking said shield in said first position.

4. (Amended) The safety shield system defined in Claim 1, wherein said one of said channel-shaped tracks includes an inwardly projecting resilient finger portion adjacent said opening resiliently biasing said outwardly inclined end portion of said one of said resilient hook-shaped fingers inwardly and releasably retaining said shield in said first position prior to retraction of said shield to said end portion of said second position and said resilient hook-shaped finger [portion] in said track initially guiding said one of said resilient hook-shaped fingers over said opening when said shield is retracted to said second position.

8. (Amended) The safety shield system defined in Claim 1, wherein said plurality of fingers each include a U-shaped portion integrally connected at one end to a tubular body portion of said clip member [and a radially projecting hook-shaped portion received in said channel-shaped tracks].

11. (Amended) A pen needle and safety shield system, said pen injector having a generally tubular body portion for receiving a container of fluid having an open end and a closure in said open end, a needle cannula assembly including a hub and needle cannula extending through said hub having a first end extending into said pen injector body and a second end extending away from said pen injector body for injection and transfer of fluid from said body to a user, said safety shield system including a generally tubular clip member having a plurality of circumferentially spaced [laterally projecting] resilient hook-shaped fingers each having an outwardly inclined end portion, a generally tubular recipricable shield including a first portion surrounding said clip member, a second portion normally surrounding said second end of said needle cannula and a plurality of spaced axially extending inwardly opening channel-shaped tracks on an inside surface of said shield receiving said laterally projecting resilient fingers of said clip member and guiding said shield axially from a first position wherein said shield second portion surrounds said needle cannula second end to a second position wherein said second end of said needle cannula is exposed, and a spring resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula second end, wherein at least one of said channel-shaped tracks includes an opening through a side wall of said shield which receives said outwardly inclined end portion of one of said resilient hook-shaped fingers when said shield is first retracted to said second position and then extended to said first position by said spring and locking said shield in said first position to limit access to said second end of said needle cannula.

14. (Amended) The pen needle and safety shield system defined in Claim 11, wherein said one of said channel-shaped tracks in said shield includes a [an inwardly projecting] resilient inwardly projecting finger portion adjacent said opening resiliently biasing said one of said fingers inwardly and releasably retaining said shield in said first position prior to retraction of said shield to said second position and said resilient finger portion in said track initially guiding said one of said fingers over said opening when said shield is first extended to said first position from said second position.

21. (Amended) A pen needle and safety shield assembly, comprising:

a pen needle having a generally tubular body portion including an open end, a needle hub member having a generally tubular body portion received over said pen needle open end, a needle cannula secured by said needle hub having a first end extending into said tubular body portion of said pen needle and an opposed second end, a clip member having a generally tubular body portion mounted on said tubular body portion of said hub member having a plurality of radially extending ribs, a generally cup-shaped retractable shield including a tubular body portion having an open end, a generally closed end portion having a central opening therethrough receiving said second end portion of said needle cannula therethrough, and a plurality of radial grooves extending through a side wall of said tubular body portion from adjacent said generally closed end portion to adjacent said open end of said tubular body portion receiving said radially extending ribs of said clip member through said side wall, and a cup-shaped cap having a plurality of inwardly projecting ribs received in said grooves in said shield to adjacent said ribs on said clip member preventing retraction of said shield when said cap is located on said shield.

Please cancel Claims 2, 3, 12 and 13, without prejudice.